REDACTED DOCUMENTS RELATED TO DOCKET 7294

Defendants' Motion and Incorporated Memorandum to Exclude the Opinions of David Garcia, M.D. and Michael Streiff, M.D. and Memorandum of Law in Support – Filed Redacted

Exhibit B – Filed Redacted

Exhibit D – Filed Redacted

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Defendants' Motion and Incorporated Memorandum to Exclude the Opinions of David Garcia, M.D. and Michael Streiff, M.D. and Memorandum of Law in Support – Filed Redacted

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S MOTION AND INCORPORATED MEMORANDUM TO EXCLUDE THE OPINIONS OF DAVID GARCIA, M.D. AND MICHAEL STREIFF, M.D. AND MEMORANDUM OF LAW IN SUPPORT

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

MOTION

Pursuant to Federal Rule of Evidence 702, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move this Court to exclude certain opinions of Plaintiffs' expert witnesses, David Garcia, M.D. and Michael Streiff, M.D.

MEMORANDUM OF POINTS AND AUTHORITIES

I. BACKGROUND

The plaintiffs' hematology experts, Dr. David Garcia, and Dr. Michael Streiff (collectively the "Doctors"), offer three categories of opinions that should be excluded. First, the Doctors submitted an addendum to their report which merely regurgitates Dr. Kessler's findings. They have no expertise in any of the topics in Dr. Kessler's voluminous report, and did no independent analysis of Dr. Kessler's conclusions. Second, the Doctors opine on physician expectations and what Bard should have, and failed to, disclose to physicians. *See* Report, attached as Exhibit A (the "Report"), at pp. 6-7. However, the Doctors do not have any expertise in implanting or removing IVC filters, developing warning labels, or corporate conduct or ethics, and testified that they largely based these opinions on Dr. Kessler's report. And, these opinions should be excluded because the only relevant inquiry is whether the physician who implanted the filter in each specific plaintiff was adequately warned. Lastly, Dr. Garcia's case-specific opinions for Plaintiff Doris Jones should be excluded in their entirety because they lack reliable methodology. *See* Jones Report, attached as Exhibit B. Accordingly, Bard moves to exclude these opinions under Rule 702 and the standards set forth in *Daubert* and its progeny.

II. ARGUMENT AND CITATION OF AUTHORITY

A. "Opinions" Regurgitating Dr. Kessler's Report Should Be Excluded.

As Judge Posner explained in *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609 (7th Cir. 2002):

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> [t]he Daubert test must be applied with due regard for the specialization of modern science. A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science. A theoretical economist, however able, would not be allowed to testify to the findings of an econometric study conducted by another economist if he lacked expertise in econometrics and the study raised questions that only an econometrician could answer. If it were apparent that the study was not cut and dried, the author would have to testify; he could not hide behind the theoretician.

Id. at 614. *See also Turner v. Burlington N. Santa Fe R. Co.*, 338 F.3d 1058, 1062 (9th Cir. 2003) (affirming the exclusion of an expert's testimony because he "intended to use [a second expert's findings] as substantive evidence of his ultimate conclusions," because the second expert's findings were not the "type reasonably relied on by experts in the particular field" and the "probative value of this otherwise inadmissible evidence d[id] not outweigh its prejudicial effect").

Here, the Doctors provide an addendum to their expert report paraphrasing Dr. Kessler's report. (*See* Ex. A, Rep., at pp. 8-9.) The Doctors claim that their review of Dr. Kessler's report (and Dr. Betensky's analysis contained in Dr. Kessler's report) somehow corroborates or bolsters their own medical opinions. However, aside from merely repeating Dr. Kessler's conclusions and providing an avenue for duplicative testimony, the Doctors fall well short of all Rule 702 and *Daubert* requirements. Dr. Streiff spent less than five hours reviewing Dr. Kessler's 270-page, 707-paragraph report, and 448 pages of schedules. (July 17, 2017, Deposition of Dr. Michael Streiff ("Streiff Dep."), attached as Exhibit C, at 295:13-17.) Dr. Garcia spent about 25 to 30 hours total working on this litigation, although he could not estimate specifically what portion of that was spent with Dr. Kessler's materials. (June 21, 2017, Deposition of Dr. David Garcia ("Garcia Dep."), attached as Exhibit D, at 33:9-22.) When asked if he read Dr. Kessler's report in its entirety, Dr. Garcia could only respond "[a]t some level, I've read it in its entirety…I would say there were some pages I read much less closely than others, but I've looked at the text of every page in some form or fashion." (Ex. D, Garcia Dep. 204:-20.) The Doctors never spoke with Dr. Kessler. (Ex. C, Streiff Dep. 302:10-12; Ex. D, Garcia Dep. 209:24-25.) And they did not contribute to, change,

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or modify any of Dr. Kessler's findings. (Ex. D, Garcia Dep. at 210:7-15.) The Doctors do not "say anything in [their] addendum about Dr. Kessler's findings that he himself doesn't say in his own report." (Ex. D, Garcia Dep. at 211:3-6.) Dr. Garcia agreed that "in drafting [the] addendum and kind of essentially regurgitating what Dr. Kessler found in his report, [the Doctors] attempt[ed] to be as accurate as possible in describing Dr. Kessler's findings." (Ex. D, Garcia Dep. 210:1-5.) Dr. Streiff agreed that they did not attempt to modify Dr. Kessler's finding in any way, testified that "[w]e read through the report and kind of pulled these right [] out of his report," and described their incorporation of Dr. Kessler's report as merely "a summary of what we read in the, in his, his report." (Ex. C, Streiff Dep. 302:15 – 304:5.)

Moreover, the Doctors admittedly lack the expertise to opine on the same material contained in Dr. Kessler's report, and do not rely on litigation-driven expert reports, or even the underlying corporate documents, in their medical practice. The Doctors are not experts in designing, engineering, testing, manufacturing, or marketing IVC filters, and are not experts in corporate ethics, FDA compliance, post-market surveillance, or reviewing internal medical device company documents (which they have never reviewed before this litigation). (Ex. C, Streiff Dep. 98:13 – 101:24; Ex. D, Garcia Dep. 83:16 – 85:12.) Dr. Garcia further explained that "I relied on Dr. Kessler's assessment of a very large body of information that I'm not, you know, familiar with or – or used to looking at and considered him – him and his conclusions to be reliable. And that – that's the basis of what I've written here." (Ex. D, Garcia Dep. 207:20 – 208:8.) The Doctors did not independently verify Dr. Kessler's methodology or review or assess any of the underlying documents or data. (Ex. C, Streiff Dep. 283:7 – 284:4; 307:6-24; 307:25 – 308:11; Ex. D, Garcia Dep. 212:8 – 213:6.) As a result, all opinions the Doctors offer based on Dr. Kessler's report should be excluded.

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B. The Court Should Exclude Opinions On Physician Expectations and Corporate Conduct.

First, the opinions contained in the Doctors' "Physician Expectations" section of their report should be excluded because they are also based on Dr. Kessler's report. (*See* Ex. A, Rep. at pp. 6-7 (opining that "in order for physicians to make reasonable risk-benefit assessments regarding filters, it is critically important that manufacturers of IVC filters continuously apprise the clinicians who order and implant IVC filters about their safety profile, performance characteristics, design problems, and internal risk assessments," and that "Bard's complete transparency about the safety profile of its IVC filters is paramount"); Ex. C, Streiff Dep. 274:23 – 277:5 (testifying that "by the time we got to [the "Physician Expectations" section], we had seen the Kessler report, and we added that in there. So I think that's, that came, it came from I guess both David [Garcia] and I's reviewing of the Kessler report…And then we went on further to make…an addendum on, that goes into, more in detail about that report, or at least several points from it"); Ex. D, Garcia Dep. 192:22 – 194:10; 196:11 – 198:11; 201:4 – 202:25 (testifying that statements in this section were based on Dr. Kessler's report).) Moreover, the Doctors provide no explanation of how Dr. Kessler's conclusions, which purport to be regulatory in nature, relate to their medical opinions. Dr. Garcia testified that he simply agreed with Dr. Kessler's and Dr. Betensky's analysis, and that "I guess one way you could say is that, assuming their analysis is true, it just strengthens the conclusions of my report" because "the information stated in this addendum only further highlights the risks of IVC filters, beyond what I could have done using publicly available peer reviewed information that's cited in my report." (Ex. D, Garcia Dep. 217:12-25.)

Second, the Doctors are not qualified to opine on what is required of manufacturers to warn physicians who implant IVC filters. The Doctors do not have any expertise in implanting or removing IVC filters, developing warning labels, or corporate conduct or ethics, and testified that they largely based these opinions on their brief review of Dr. Kessler's report. The Doctors have never placed or removed an IVC filter. (Ex. C,

Streiff Dep. 97:25 – 98:2; Ex. D, Garcia Dep. 52:24 – 53:2.) Dr. Garcia admitted that he does not make the ultimate decision of whether a patient should receive a filter, but is sometimes part of the decision-making process with other physicians. (Ex. D, Garcia Dep. 54:7-18.) He does not have any role in deciding what brand filter to place. (Ex. D, Garcia Dep. 56:8-16.) Similarly, Dr. Streiff makes recommendations in consultation with other physicians, does not place filters himself, and stated "I defer to my colleagues in [interventional radiology] what, you know, what filter they use…whether they use permanents or an optional filter." (Ex. C, Streiff Dep. 133:22 – 134:20.) And, the Doctors have no experience developing device labeling or warnings that would otherwise allow them to opine on what physicians should expect regarding the risks or warnings of IVC filters. (Ex. C, Streiff Dep. 101:23 – 102:9; Ex. D, Garcia Dep. 86:5-12.)

Finally, the Doctors' personal speculation on what physicians expect regarding IVC filters is irrelevant and does not fit the facts of this case. The only relevant inquiry for the plaintiffs' failure to warn claim is whether their implanting physicians were adequately warned under their respective jurisdictions' laws. *Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1130 (D. Ariz. 2001) ("The trial court 'must ensure that the proposed expert testimony is relevant to the task at hand,…i.e., that it logically advances a material aspect of the proposing party's case.'") (*quoting Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir.1995)).

C. Dr. Garcia Did Not Use Reliable Methodology or Analysis for Jones-Specific Opinions.

[redacted]

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[redacted]

[redacted].

III. CONCLUSION

The Doctors' opinions based on their brief review of Dr. Kessler's report, including their opinions regarding physician expectations, are not only inadmissible under Rule 702, but are also unhelpful and unreliable under *Daubert*. And, Dr. Garcia's opinions in

Plaintiff Jones' case lack any scientific support or methodology. Accordingly, these opinions should be excluded in their entirety.

DATED this 24th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that August 24, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

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Exhibit B – Filed Redacted

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SCHOOL OF MEDICINE

Department of Medicine

Division of Hematology

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June 5, 2017

Dear Mr. O'Connor:

At your request, [redacted].

It is my opinion [redacted].

In a [redacted].

I therefore also hold the opinion tha[redacted]

Along with my previously submitted general report I provided a copy of my CV and fee schedule, which have not changed.

My opinions are given to a reasonable degree of medical certainty and probability.

David A. Garcia, MD
Professor, Division of Hematology

REDACTED DOCUMENTS RELATED TO DOCKET 7294

Exhibit D – Filed Redacted

Exhibit D

Deposition of:

David Garcia , M.D.

June 21, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

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some discussion, which included counsel, that let us to think it -- it might be instructive to include a particular quote from that deposition in our report.

Q. Okay. Outside from reading Dr. -- I mean, Mr. Ganser's deposition, you haven't read any other fact witness depositions?

A. Not that I recall --

Q. Okay.

A. -- at the moment.

Q. And you haven't read any expert depositions?

A. No.

Q. Okay. All right. Have you reviewed any medical records?

A. Yes, I've reviewed the records of -- of Ms. Jones, at least the ones that were provided to me by plaintiff counsel.

Q. Okay. Do you have a copy of those records?

A. Electronically, I do --

Q. Okay.

A. -- yeah.

MR. LERNER: Joe, can you make those available, the records for Ms. Jones?

MR. JOHNSON: Yes.

Q. (By Mr. Lerner) Do you know -- did you receive the entirety of the records, or do you know?

A. We met from nine till about three, so six hours.

Q. And did you charge just for six hours, or you're charging for the entire day?

A. I'm going to just charge for six hours, but I also did a little bit of prep time last night and early this morning -- probably another couple of hours worth that I'll charge for.

Q. Okay. So outside of your prep work with counsel for the deposition, we're still looking at about 25-30 hours total time for you to submit your report?

A. Yes.

Q. And does that include the amount of time you spent on the Jones case?

A. Yes, mm-hmm.

Q. Okay. As far as how you spend your time for those 30 hours, you don't have a breakdown of those -- that time?

A. No. I mean, if what you mean by that is, did I submit this number of hours reading materials and this number of hours talking to lawyers and this number of -- no.

Q. Okay. So how do you track your time then, in order to submit your time?

A. I use an app on my phone called Gleeo Time

University of Washington in 2012, had you ever taught any classes specific to IVC filters?

A. Not that I can think of. I mean, I've certainly given presentations about the general treatment and prevention of venous thrombosis, which would have often included some mention of IVC filters.

Q. Okay. And when you were at these various academic institutions, where you were either an instructor or a professor, did you teach class -- actual classes?

A. Yes.

Q. Okay. And then you also had hands-on training with the residents --

A. Yes.

Q. -- and fellows? Okay.

A. Both.

Q. Did you ever train any of your residents or fellows in IVC filter -- or about IVC filters?

A. Yes, I would say that I frequently talk to trainees of all levels about IVC filters and the -- the clinical circumstances in which they're, you know, contemplated and -- and we talk about the risks and benefits associated.

Q. Have you ever placed an IVC filter?

A. No.

Q. Okay. And you've never removed an IVC filter?
A. Neither one.
Q. Okay. And the focus of your scholarship has primarily been on what?
If someone were to ask you -- "This is the area that I focus in" -- what would you say?
A. I usually answer -- laypeople -- that blood clots and blood thinners.
Q. Okay. And because -- that you treat people that sometimes have blood clotting disorders, sometimes you interact with people that may need -- may need to be treated with IVC filters?
MR. JOHNSON: Form.
A. I would say that, very rarely, there are situations where I have recommended an IVC filter.
Q. (By Mr. Lerner) Okay. Do you still recommend IVC filters today?
A. I recommended one just last month.
Q. Okay. And what was the situation for that?
A. A patient who suffered pulmonary embolism, and shortly after that suffered intracranial bleeding while on anticoagulant therapy. And I considered that the risk of continuing anticoagulation in that patient was prohibitive.
And the risk of additional thrombosis was high

enough that, although I have serious doubts about the magnitude of the benefits of filters, I felt that -- that the possibility that the filter could be beneficial to that patient outweighed its various risks. But we had a long discussion with her and her family about that.

Q. Okay. And then tell me about that a little more. When you are involved in the decision -- you are involved in the decision for patients about whether to recommend or not an IVC filter?

A. Very often.

Q. Okay. But you're often, I would imagine, talking to other physicians who are also part of that decision-making process?

A. I would say so. Although because of my background and expertise -- at least in my own institution -- I would say there's a lot of deference to my opinion.

Q. Okay. Do you have any protocols in place at your institution about the placement of IVC filters?

A. I don't know of any, no.

Q. Okay.

A. Any written protocol, no.

Q. And there are IVC filters that to this day are being placed in your facility --

A. My -- my -- my default, in the rare instances where I would recommend a filter, would be to recommend one that could be retrieved.

Q. (By Mr. Lerner) Okay. And then what was the filter that you recommended a couple of months ago or last month?

A. I don't know.

Q. Okay. So as far as what the brand or model filter that's actually used, do you make that decision or the doctor -- like the interventional radiologist who actually placed the filters, do they make that decision?

A. The interventional radiologist makes it.

Q. Have you ever been part of a decision-making process for the brand or model of filter that's going to be used?

A. No.

Q. Okay. You defer that to the people that are actually placing the filters?

A. That's right.

Q. Okay. And in your institution, who are those folks that actually place the filters?

A. Interventional radiology.

Q. Okay. Do they place IVC filters, to your knowledge, without consulting with you?

A. Well, they don't -- yes, but they -- they

Q. You're used to 12-hour days, 15-hour days, so that's no big deal. All right. I want to talk a little about your qualifications. You're a hematologist, and you talked about that. In lay terms, can you explain that again?

A. Sure. I take care of patients with blood disorders in general. I've been trained to take care of a variety of blood disorders, including blood cancers, abnormal blood counts, abnormal amounts of iron in the body.

But -- but my practice is certainly -- even from before I was a board certified hematologist and certainly including after my practice -- is focused on patients either with or at risk for thromboembolic disease.

Q. Okay. I want to ask you a few questions, but I think the answer is going to be no too. But I just want to make sure. You would agree that -- do you have any engineering background?

A. No.

Q. Okay. So, you're not a -- you're not offering yourself as an expert in design or engineering principles?

A. No.

Q. Okay. And you're not an expert in bench

testing?

A. No.

Q. Okay. You're not an expert in the manufacture of IVC filters?

A. No.

Q. You have no experience marketing IVC filters?

A. No.

Q. You have no education or training regarding corporate -- corporate ethics?

A. No.

Q. Okay. And then you're not an expert in summarizing medical device company documents?

MR. JOHNSON: Form objection.

A. I -- I would -- I've never thought of myself as an expert in summarizing medical device company documents.

Q. (By Mr. Lerner) That's not something you routinely do, is review internal company documents as part of your clinical practice?

MR. JOHNSON: Form.

A. No, I would say not.

Q. (By Mr. Lerner) I mean, have you ever done that -- reviewed internal company documents -- to make decisions as part of your clinical practice?

A. Prior to this litigation, I -- I have never

had occasion to -- to do that or the opportunity to do that.

Q. Okay. And then you're not an FDA expert, right?

A. No.

Q. You're not holding yourself as an FDA expert?

A. I don't consider myself an FDA expert, no.

Q. Or an expert in regulatory compliance?

A. No.

Q. And you've never worked in post market surveillance in any company?

A. No.

Q. Have you ever been on any boards with any companies?

A. Well, I've served on advisory boards, which are usually constituted as a one-time event -- involve so-called key opinion leaders, spending a day somewhere. The company presents some data about a product; says, "We'd like to get your opinions on strengths and weaknesses of our product."

Q. Okay.

A. So if you consider that -- I -- I have served on that sort of board, but I've never been on a -- on a board of a company that meets with any regularity.

Q. Okay. And for those times, where you've kind

of reviewed or provided your -- your background and information about the benefits of a product, has that ever involved IVC filters?

A. No.

Q. Okay. And you've never developed warnings for products?

A. No.

Q. Never developed any warnings for IVC products?

A. No.

Q. So, you wouldn't consider yourself a warning expert?

A. No.

Q. Okay. All right. I want to talk a little bit more about deep vein thrombosis and pulmonary embolism.

Can you describe the difference between deep vein thrombosis, DVT, and a pulmonary embolism?

A. Sure. We think of deep vein thrombosis and pulmonary embolism, first of all, as being part of the same spectrum of the disease. Deep vein thrombosis refers to the formation of blood clots in deep or large vessels.

Most commonly, these are located in the legs, although such clots can form elsewhere in other deep veins. Typical symptoms are pain, swelling. Some patients compare it to a charley horse or muscle cramp.

the relative safety or efficacy could be made based on those observational studies?

MR. JOHNSON: Form.

A. Because as I said -- as I said earlier, observational studies cannot be relied on to determine relative efficacy or safety between two treatment options.

But in this case, what -- I'm merely -- I'm merely gleaning from the observational studies that if you put an IVC filter in 100 people, about five of them will have thrombosed their vena cava over the next one to two years.

I can tell you, from taking care of patients for 20 years and again from other published literature, that event -- IVC thrombosis -- almost never occurs in the absence of an IVC filter.

So, I'm very comfortable in that particular instance concluding from the observational cohort study that there -- that this risk is attributable to IVC filters. And I have a pretty good idea of what the magnitude of the risk is.

Q. (By Mr. Lerner) Okay. All right. Let's go down to the next paragraph here. You say that, "Thus, in order for physicians to make reasonable risk-benefit assessments regarding filters, it's critically important

that manufacturers of IVC filters continuously apprise the clinicians who order and implant IVC filters about their safety profile, performance characteristics, design problems, and internal risk assessments."

So, what are you saying there?

A. Well, I mean, I think this is a -- a statement that could apply to the manufacturer of any device or medication that's going to be prescribed or deployed by a -- by a treating physician. But it's perhaps --

I think we wanted to emphasize it here, because when you have an intervention -- the benefit or efficacy of which is highly questionable or poorly established -- ensuring that the doctors who are choosing to use it know as much detail as possible about its risks, has heightened importance.

Q. What does that mean in practical terms? Are you suggesting that every time there's an adverse event with a medical device, that the manufacturer should be reporting that to every physician that uses the device?

A. No. I'm not trying to suggest an unreasonable burden on any corporation. But I think -- but I do think that -- I think there's -- I do think there's a strong requirement that --

I guess, I think that a company should have a perhaps even lower than average threshold to track and

report risk when a -- when a device or intervention has poorly established or -- or unestablished benefit.

Q. Are you familiar with the FDA regulations about what information can and cannot be provided to physicians by manufacturers?

A. I'm not.

MR. JOHNSON: Form.

Q. (By Mr. Lerner) And you wouldn't want manufacturers providing unreliable information, correct?

A. No, I wouldn't.

MR. JOHNSON: Form.

Q. (By Mr. Lerner) And you wouldn't want manufacturers to be providing incomplete information?

MR. JOHNSON: Form.

A. Well, I think -- I mean, I think that the challenge there is -- who's making the judge to whether it's complete or incomplete and -- and what context it's being provided.

I certainly wouldn't want a manufacturer to be providing information that would mislead a physician in either direction, over- or underestimating the risk.

Q. (By Mr. Lerner) Yeah. You want manufacturers providing you with reliable scientific information, correct?

MR. JOHNSON: Form.

judgment.

Q. (By Mr. Lerner) Is there any other manufacturer, that you're aware of, that's providing you the information that you say should be provided by manufacturers?

A. Well, I can't think of one. But, I mean, I also can't think of a -- of an intervention or a device that is so widely used, at least in my sphere of practice, with so little high-quality evidence for its benefit.

Q. What do you mean here when you say that companies should be providing internal risk assessments? What does that mean?

A. Well, the -- I think what -- what we intended to say there with Dr. Streiff is that if a company makes an internal -- what's originally an internal determination that a device or product is associated with a particular risk that has not been publicly disclosed, then -- then they need to publicly disclose it -- I mean, whether it's to regulators or to practicing physicians. But somebody needs to know about it.

Q. In the next sentence you say, "In addition, filter manufacturers have a key obligation to report the experiences of other physicians who have reported

serious complications, as well as any available relevant inter-device comparisons or emerging studies that compare IVC filter implantation to other management strategies."

Let's break that down. First, you say, "filter manufacturers have a key obligation to report the experience of -- experiences of other physicians who have reported serious complications." What do you -- what do you base that on?

A. Well --

MR. JOHNSON: And I'm going to ask that you read the next sentence, because I think they -- they do go hand in hand.

MR. LERNER: I'm going to -- you can redirect, if you want to.

MR. JOHNSON: I just don't want you to take his sentence out of context, because it goes on to say, "In other words ..."

A. Well, I mean, what I would say is the -- a physi -- an individual physician, maybe in talking to -- even in talking to his or her colleagues, has very limited bandwidth to assess the risks of -- of a device or even a therapy.

And a company or manufacturer is a ware -- is a warehouse, a clearinghouse, that is set up to

potentially receive, you know, all or many reports of complications from a much wider scope of observation, if you will.

And if a company is getting reports from far and wide of complications -- which are maybe happening infrequently at any given institution, but with some frequency in the world at large -- they're the only entity that has the ability to provide that perspective to an individual physician, who is him or herself just only able to focus on what's going on in their immediate surroundings.

Q. (By Mr. Lerner) Are you aware that reports of complications are reported to the MAUDE database?

A. I'm aware of the MAUDE database. But I believe that experts like Dr. Kessler and others, who are much more familiar with regulatory history than I am, believe or have evidence to think that there's underreporting when it comes to the MAUDE database.

Q. But individual adverse events themselves, like case reports, they're on the lowest end of the spectrum of the hierarchy of scientific evidence, correct?

A. That is true. In isolation, a case report is at the lowest end.

Q. I mean, even if not -- not in isolation, if you have various adverse events, spontaneous reports,

information that pharmaceutical medical device companies under FDA regulation can provide to the public?

A. No.

Q. Okay. Let me ask you this next question. So, the last paragraph here -- well, second-to-last sentence -- you say, "In other words, in order for physicians (and ultimately patients) to properly assess the risks versus the benefits of IVC filters (along with other available therapies), it is our opinion that Bard's complete transparency about the safety profile of its IVC filters is paramount."

What was the purpose of adding that statement to your report?

A. I think it's just clarifying the -- the prior statement in -- in that -- again, if you -- I think I said this earlier, but I'm going to resay it.

When you have an intervention for which the efficacy is poorly established or not established, the importance of notifying physicians about any possible risk or safety concern associated with that intervention becomes even higher than -- than treatments, where at least we know there's -- there is some well-documented benefit.

Q. Let's continue with the last sentence here. "We share the sentiments of Bard's former director of

regulatory affairs that: 'Transparency in matters that affect patient safety should be embraced as a primary corporate obligation.'"

So you read the one deposition of Chris Ganser, and you --

A. Right.

Q. -- you decided on your own to add this one sentence here to your report?

A. I mean, I decided in -- in conjunction with Dr. Streiff, in the various back-and-forth discussions we had, yeah.

Q. So, are you implying here that somehow -- that Bard has not been transparent about the safety profile of its IVC filters?

A. Well, I think the -- I mean, I don't consider that to be the principal opinions in -- that I have in this matter, but I -- but I am concerned by some of the things that I've been shown by plaintiff counsel.

I mean, just -- and if you -- I can cite a couple of examples, but -- but, yeah, I do have some concern that Bard is not completely transparent.

Q. Okay. And the reason why you have that concern, is it based on the Dr. Kessler report that you reviewed?

A. That's a big part of it, yep.

(Exhibit-11 marked for identification.)
MR. JOHNSON: I don't need one, Matthew.
MR. LERNER: I figure you have the copy of the report in front of you.
MR. JOHNSON: I do.
Q. (By Mr. Lerner) All right. So you have a copy of Exhibit-11, which is your addendum?
A. I do.
Q. Okay. Did you read Dr. Kessler's report?
A. I've read it, yes.
Q. Did you read it in its entirety?
A. At some level, I've read it in its entirety.
Q. How many pages is that report, do you recall?
A. In the hundreds.
Q. And you read all those pages in detail?
A. I would say there were some pages I read much less closely than others, but --
Q. Okay.
A. -- I've looked at the text of every page in some form or fashion.
Q. And what was the reason why you read his report?
A. Because, as I recall -- again in discussions with counsel and Dr. Streiff, we -- it was felt that it would provide important background information.

A. That sounds familiar, but I can't remember why.

Q. Do you recall reviewing his expert report in this case?

A. I don't think I reviewed a --

Q. And you --

A. -- regulatory report.

Q. -- didn't review his deposition either?

A. No.

Q. Did you read the expert report of Dr. Ronald Thisted?

A. No.

Q. Do you know who he is?

A. No.

Q. Do you think it's appropriate to only consider one party's position in developing their opinion?

MR. JOHNSON: Form.

A. I mean, I guess -- I guess I do, because I -- I did that, so --

Q. (By Mr. Lerner) Well, just because you did it, doesn't mean you have to agree to it. Do you think that is appropriate?

I mean, you're an evidence-based physician. You've told me that throughout this deposition today. So, is it appropriate for you -- who pride yourself on

being evidence-based -- to rely on the opinions of a single expert who is a paid advocate for the plaintiffs?

MR. JOHNSON: Form.

A. Well, I relied on Dr. Kessler's assessment of a very large body of information that I'm not, you know, familiar with or -- or used to looking at and considered him -- him and his conclusions to be reliable. And that -- that's the basis of what I've written here.

Q. (By Mr. Lerner) Okay. But, again, do you think that it's appropriate for you to consider the opinions of only one side of the story?

MR. JOHNSON: Form.

A. Well, I mean, I'm willing to look at other representations and -- and consider them.

Q. (By Mr. Lerner) But you haven't done that --

A. I have not as of today.

Q. Right.

A. Yeah.

Q. And you're not an FDA expert, to begin with?

A. I'm not.

Q. And Dr. Kessler was offering regulatory opinions?

A. Correct.

Q. Okay. As a course of your work at the university and part of your clinical practice, do you

rely on litigation-driven expert reports to make -- to form opinions?

MR. JOHNSON: Form.

A. No.

Q. (By Mr. Lerner) Have you ever done that?

MR. JOHNSON: Form.

A. No.

Q. (By Mr. Lerner) So, this is the first time --

A. To -- to form opinions about patient care?

Q. Right.

A. No.

Q. So, the first time you've ever done that -- regarding a litigation expert report to form opinions -- is in this litigation, correct?

MR. JOHNSON: Form.

A. As far as I can remember.

Q. (By Mr. Lerner) Yeah. Your report is -- your addendum -- Dr. Kessler's spoken to various sections, correct?

A. It is.

Q. The addendum kind of references the finding of Dr. Kessler, right?

A. Right.

Q. Have you ever spoken to Dr. Kessler?

A. No.

Q. So in drafting your addendum and kind of essentially regurgitating what Dr. Kessler found in his report, did you attempt to be as accurate as possible in describing Dr. Kessler's findings?

A. I did.

MR. JOHNSON: Form.

Q. (By Mr. Lerner) You didn't try to modify in any way Dr. Kessler's findings?

A. That was certainly not my intent, no.

Q. (By Mr. Lerner) And so you didn't change any of the findings from Dr. Kessler's report, in part of the --

A. No.

Q. -- addendum there?

A. No.

Q. So you included seven numbered paragraphs, repeating what Dr. Kessler himself says in his own report?

A. Yes, because the -- while there's publicly available evidence of IVC filter risks that you and I have discussed earlier in today's deposition, this -- these elements of Dr. Kessler's report, I thought, highlighted additional risks associated with the Bard product in particular, that were not necessarily publicly known about or available to practicing doctors

and -- and -- but were relevant in the overall risk/benefit discussion that -- that my report entailed.

Q. Okay. So you don't say anything in your addendum about Dr. Kessler's findings, that he himself doesn't say in his own report, true?

A. Correct.

Q. Okay. In other words, you are repeating what Dr. Kessler found, without changing anything?

A. Essentially, yes, in the context of my report -- or to add context to my report with Dr. Streiff, yes.

Q. But Dr. Kessler's findings do not factor into your actual analysis in this report, true -- your whole report that we just went through?

A. Well, only -- only in that they -- only to the extent that they provide additional information about risk, which we haven't talked about much today. But the risks associated with IVC filters, yeah, because that's a major subject of my report -- is risk benefit, yeah.

Q. No one asked you, as part of your analysis, to perform a regulatory analysis?

A. No.

Q. And it's not necessary for you to conduct any kind of regulatory analysis to reach the opinions that you set forth in your expert report; is that true?

A. True.

Q. Yeah. And you understand that Dr. Kessler prepared this report for use in litigation?

A. Yes.

Q. Okay. Can you describe the methodology that Dr. Kessler employed in reaching his opinions?

A. No.

Q. Okay. Did you independently verify Dr. Kessler's methodology?

A. Not in any great detail. I mean, for example, I've looked at the paper by Murray Ash and made sure that my own assessment of that paper was consistent with Dr. Kessler's.

And I read the report provided to Dr. Kessler by Dr. Betensky regarding analysis of adverse reports, just to generally make sure I shared his conclusions. But -- but beyond that, no.

Q. Okay. Have you reviewed any Bard FDA submissions or correspondence?

A. Not that I recall.

Q. Did you independently review and assess the reliability of the underlying data that Dr. Kessler relied on?

A. Not beyond what I just told you.

Q. Okay. Did you check or test any of the

assumptions that Dr. Kessler made about the data that he analyzed?

A. No.

Q. Did you verify the documents that Dr. Kessler reviewed actually show what he says they show?

A. Not beyond what I just told you.

Q. Okay. So you assumed, for purposes of your report, that Dr. Kessler employed reliable methodology?

A. Yes, I did make a lot of assumptions to that effect.

Q. And you assumed, for purposes of your report, that Dr. Kessler utilized reliable underlying data?

A. Yes.

Q. Okay. And, as we sit here today, you have no independent information allowing you to vouch for the reliability of Dr. Kessler's opinions?

A. No, other than my independent review of the Ash paper and the Betensky analysis that I just mentioned.

Q. Did you review the Dr. Betensky report?

A. Not a report, no. Only the --

Q. Referenced by Dr. Kessler to Dr. Betensky?

A. Well, no. Among the materials that were sent to me included -- I would call it more of an analysis than a report, that Betensky did, looking at

Q. -- correct?

So you don't know if there are other facts or data out there that Dr. Kessler or Dr. Betensky admitted, that may affect whether you agree with their opinions?

A. No, I -- I don't. But I would -- again, I would just say that I considered this addendum about Kessler's report to be information that strengthens the rest of my report with Dr. Streiff. But my report with Dr. Streiff would still stand, even independent of all this information.

Q. So, you read Dr. Kessler's report. You read Dr. Betensky calculations. You didn't perform any independent analysis, but simply kind of agreed with their analysis?

A. Correct. I guess one way you could say is that, assuming their analysis is true, it just strengthens the conclusions of my report.

Q. Okay. And how so?

A. Because their -- the facts stated in -- or the information stated in this addendum only further highlights the risks of IVC filters, beyond what I could have done using publicly available peer reviewed information that's cited in my report -- the rest of my report.

list to us.

MR. JOHNSON: I will.

MR. LERNER: Okay.

MR. JOHNSON: I will. And I apol -- I mean, I had intended to do that, and I apologize for that.

Q. (By Mr. Lerner) Did you review any imaging?

A. No.

Q. And I guess since you're not a radiologist, would you be reviewing--

A. No.

Q. -- imaging?

A. I mean, in fact, the plaintiff attorneys, I'm -- I'm pretty sure, offered me the opportunity to do so. And I declined because I wouldn't have the expertise.

Q. Okay. So, you wouldn't be qualified to review imaging?

A. No.

Q. Okay. That's what diagnostic radiologists do?

A. Absolutely.

Q. Okay. Now, did you talk to any of the plaintiffs' medical experts?

A. No.

Q. Okay. Did you review any of the expert reports of any available medical experts for Ms. Jones?

A. No.
Q. Okay.
MR. JOHNSON: You mean beyond treaters' records, the --
MR. LERNER: Beyond the treater records.
MR. JOHNSON: Yes.
MR. LERNER: Actual retained experts by the plaintiff.
A. That's what I thought you meant. And no.
Q. (By Mr. Lerner) Did you talk to Ms. Jones?
A. No.
Q. Okay. Have you talked to any of Mrs. Jones's physicians?
A. No.
Q. So in order to write this report for Ms. Jones, am I right that you reviewed medical records?
A. Yes.
Q. Okay. Is there any particular medical literature that you relied upon in preparing your report?
A. No, other than -- again, I would go back to PREPIC1, eight-year follow-up, and the evidence that an IVC filter can induce the risk of thrombosis and a -- and a general knowledge that other published literature suggest that to be the case. I would -- I would say

there's no -- there's no specific evidence that I relied upon for this report.

[redacted]

[redacted]

Q. And so do you know whether those situations happened here?

A. I don't know.

[redacted]

[redacted]

opinions. The first opinion that you have is that "the

[redacted]

Q. Okay. Have you ever seen a fractured filter strut, causing thrombosis, reported in the medical literature?

A. No.

Q. And there are other risk factors for the development of in situ thrombosis, correct, beyond what you're saying here is a filter strut?

A. Yes.

Q. Can you describe some of the other risk factors for development of in situ thrombosis?

A. Sure. Compression of a vessel, presence of central venous catheter, prosthetic mechanical heart valve would be a few.

[redacted]

MR. JOHNSON: Form.

[redacted]

[redacted]ot. We can't always identify what they are, but --

Q. (By Mr. Lerner) Right.

A. [redacted]

Q. Are you aware of anything in the medical literature that supports the finding that a fractured fragment has contributed to causing thrombosis?

A. No, I'll be -- I'll be extrapolating, though, from data that I think does establish that an intact filter promotes thrombosis formation.

Q. But an intact filter, the size of that is very different from a fragment --

A. Yes.

Q. -- from one of the arms or legs?

A. But I'm not aware that surface area or size has any correlation with thrombosis risk, when it comes

to putting a foreign object in the -- in the circulating blood.

Q. But do you have any evidence, either way, that size doesn't matter?

A. No, I don't have any evidence that it does or does not.

Q. Right. And the PREPIC studies that you talked about did not study or examine thrombosis in fractured filters?

A. Correct.

Q. Okay. And you're not aware of any studies -- scientific studies that seek to analyze the potential impact of filter fragments, causing thrombosis?

A. No.

Q. Okay. And as far as the condition of this fragment of an undetermined size that -- in one of her lungs, do you know whether it's endothelialized?

A. My guess is that it has been endothelialized over time, because most -- most things that are in -- dwelling in a blood vessel, grow an endothelial lining around them.

Q. Okay. And what's a good way to explain what that is, in layman terms? Is that tissue growth over the fragment?

A. [redacted]

[redacted]

A. [redacted]

[redacted]

Q. Are you able to quantify what that risk is, that increased --

A. No.

Q. -- risk is?

And then are you able to point to any literature or scientific studies that would help quantify that she's at an increased risk?

A. No, other than again extrapolating from what we know about intact filters.

Q. And, then, doesn't the -- Strike that.

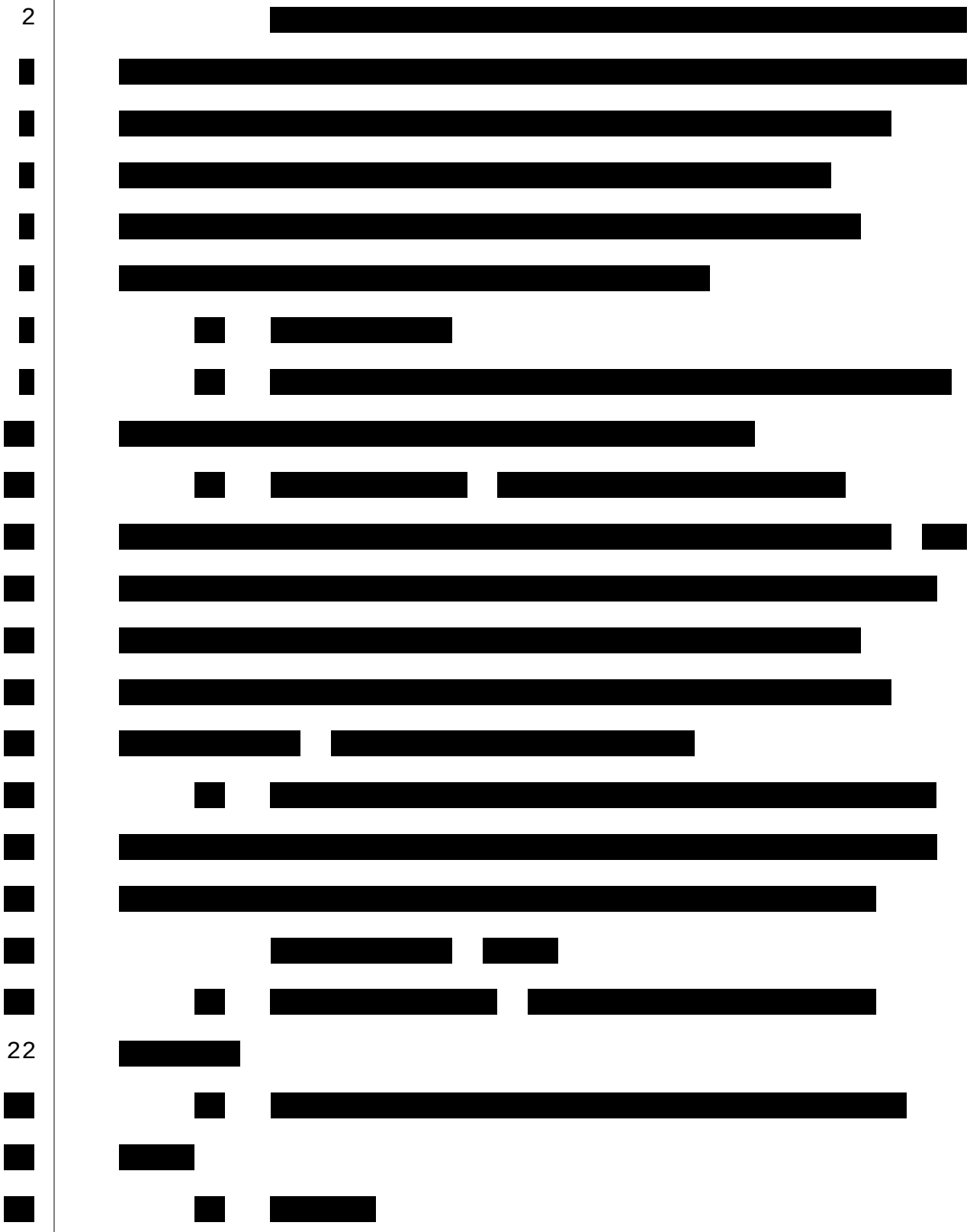
If the fragment has in fact at some point caused injury to the inner wall, the pulmonary artery, do you know when that would have occurred?

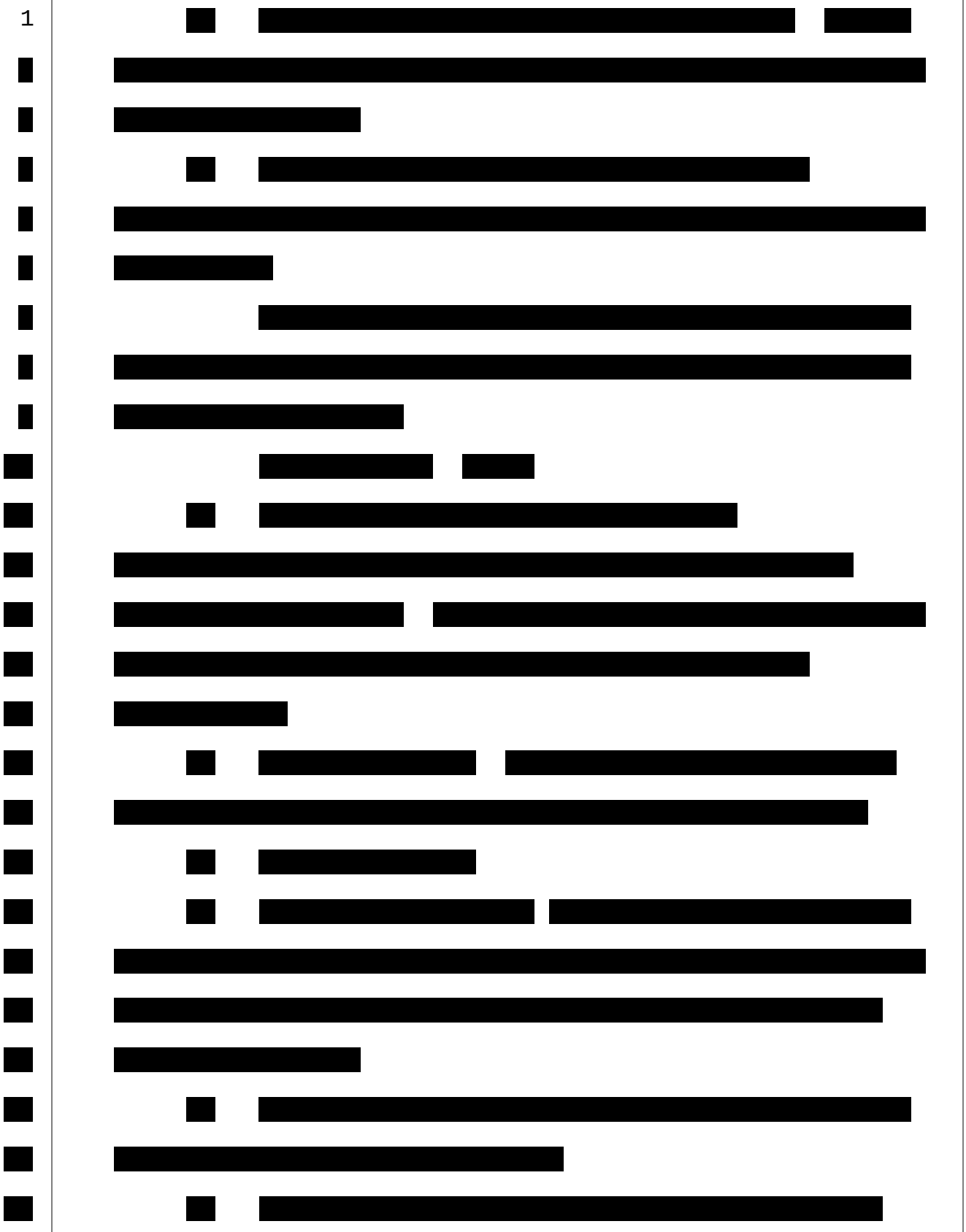
A. I would assume shortly after the frac -- the -- it fractured and migrated there.

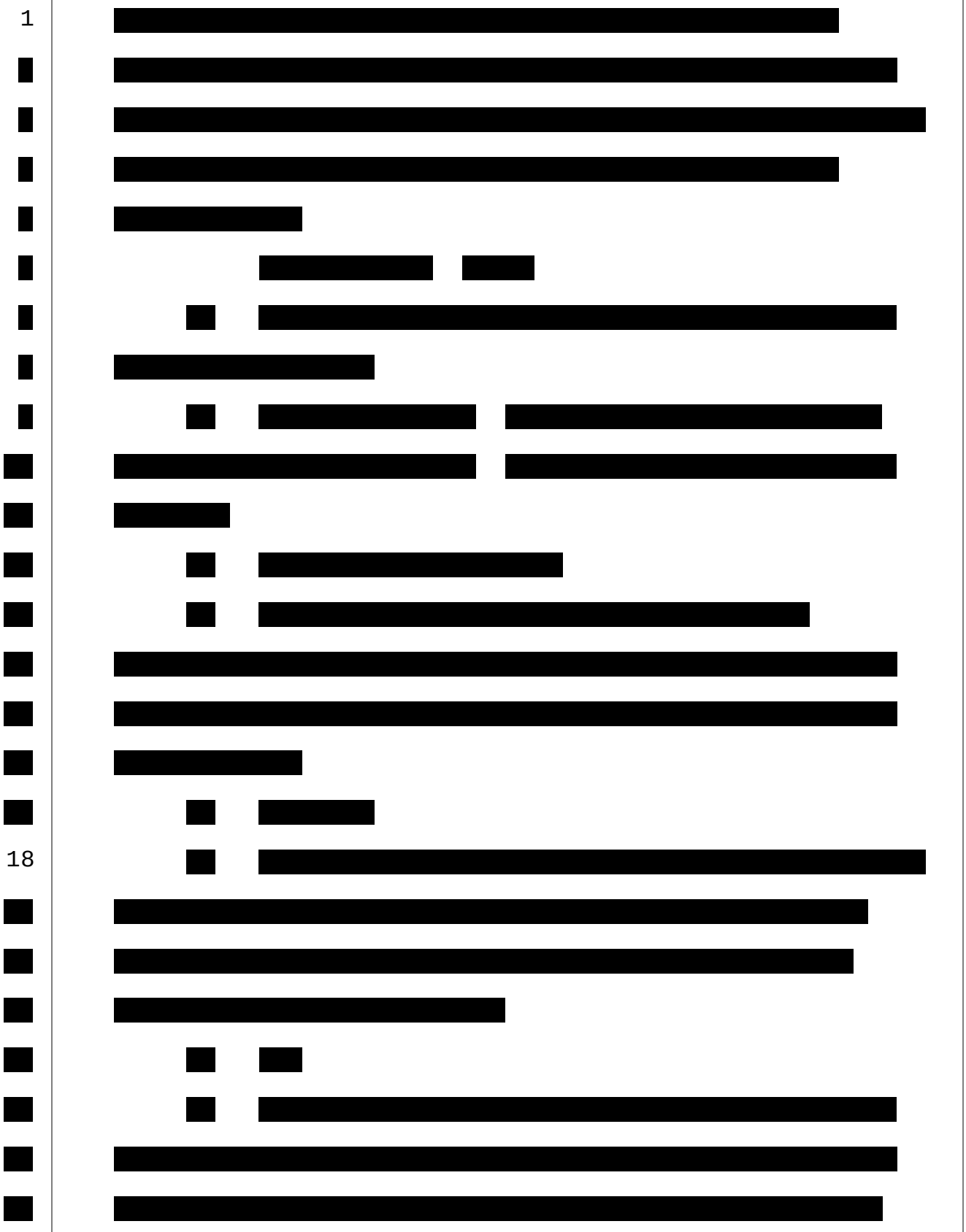
Q. And wouldn't the wall that -- pulmonary artery then heal?

A. (Witness moves head up and down.)

Q. -- right?







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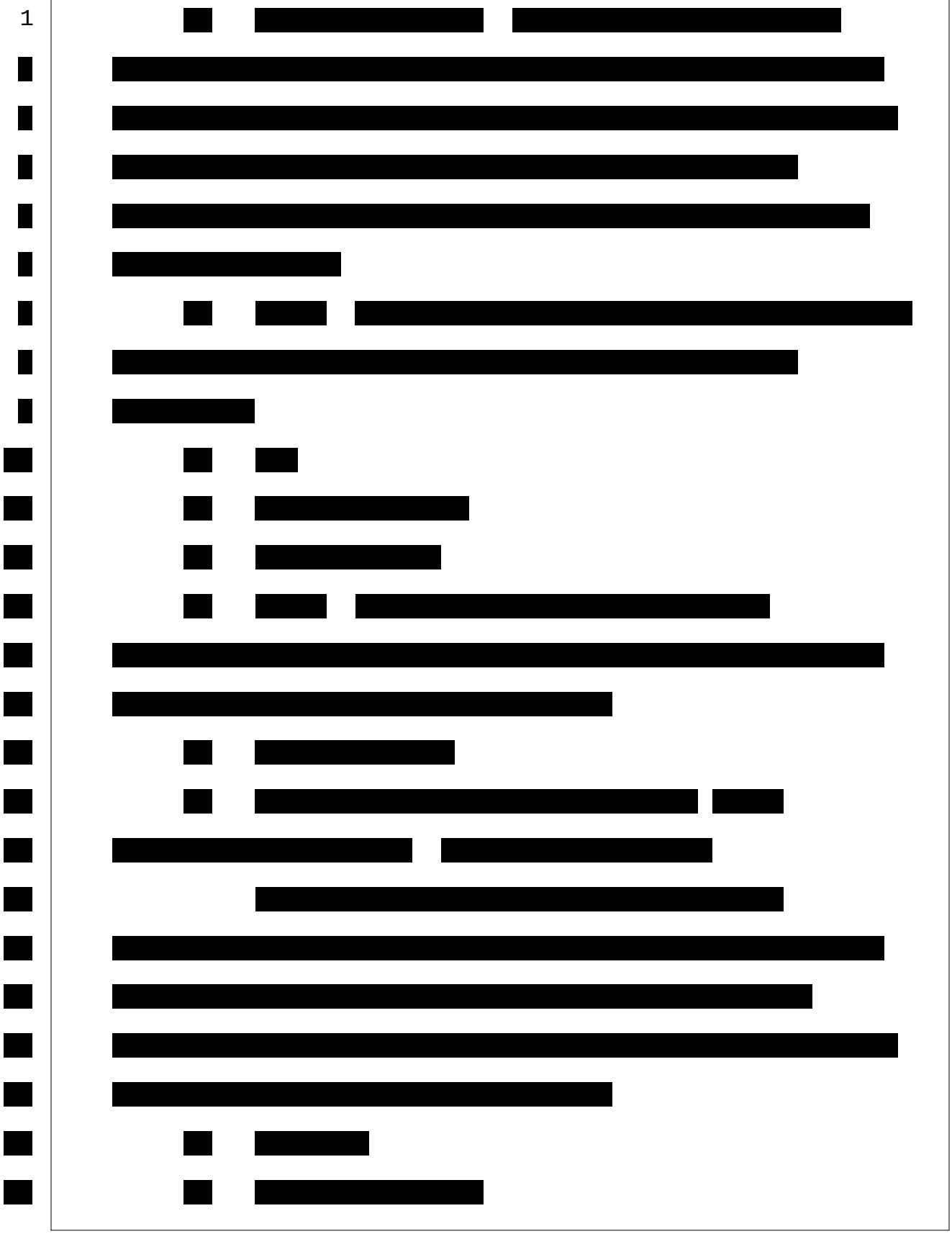
THE VIDEOGRAPHER: Going off the record. The time is 3:47.

(Recess taken from 3:46 p.m. to 3:49 p.m.)

THE VIDEOGRAPHER: Back on the record. The time is approximately 3:50.

Q. (By Mr. Lerner) Dr. Garcia, we're towards the [redacted]



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MR. LERNER: Okay. All right. Those are all the questions I have.

MR. JOHNSON: Dr. Garcia will read.

THE VIDEOGRAPHER: This is the end of Media No. 3. This ends this deposition. The time is approximately 3:58.

(Deposition concluded at 3:57 p.m.)

(Signature reserved.)